The Rejection under 35 U.S.C. § 101

Claims 20 to 23, 25 and 27 to 33 are rejected under 35 U.S.C. § 101 because they are allegedly drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of Paper Numbers 8 and 12 and section 5 of Paper No. 20.

In Paper No. 8 (mailed April 18, 2000), the Examiner noted that the receptor protein PF4AR was an "orphan receptor", and that the act of invention was not yet completed because a "specific and credible" utility had not yet been found. The Examiner further relied on *Brenner v. Manson* for the notion that a broad utility is insufficient to meet the requirements of 35 U.S.C. § 101, which requires a utility more akin to "immediately obvious" or a "real world" utility. "In the absence of a knowledge of the natural ligands or biological significance of this protein, the Examiner alleged that there is no immediately obvious patentable use for it." Paper No. 8, Section 4, page 3.

Applicants attempted to traverse the Examiner's rejection in their response on October 16, 2000 by pointing out on page 60, lines 23-29 of the specification that antibodies against to polypeptide receptor of Figure 4 would be a useful immunohistochemical diagnostic for monocytic cells and PBLs (peripheral blood lymphocytes) since such cells express the polypeptide of Figure 4. The use of antibodies that bind PBLs in a tissue sample would be useful to detect, identify, and/or separate these cells for analysis or study.

In Paper No. 12 (mailed December 22, 2000), the Examiner argued that Applicants' asserted utility is akin to a cell marker, and that utility as a tissue-specific marker is not a substantial or specific utility. Specifically, the Examiner articulated:

> All cDNAs encoding human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any polynucleotide encoding a protein which is expressed in a tissue specific manner can be employed to detect the tissue or cell type in which it is expressed in a sample. Alternatively, a polynucleotide encoding a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample.

Continuing, the Examiner found such utilities (*i.e.*, the "ubiquitous utilities") to be analogous to the assertion that a particular protein can be employed as a molecular weight or chromosomal marker. The Examiner further recited analogies referring to the use any purified compound having a known structure to use as an analytical standard.

Citing *Brenner*, the Examiner then argued that Applicants' polynucleotide claims represent a human protein of "unknown biological significance", and would represent a monopoly, the " 'metes and bounds' of which 'are not capable of precise delineation' ".

Finally, the Examiner concluded his rejection by suggesting that the absence of recognition in the specification of the significance of the claimed receptor as an HIV co-receptor is precisely the monopoly grant of a "vast, unknown and perhaps unknowable area" that blocks off "whole areas of scientific development, without compensating benefit to the public" that was anticipated in *Brenner*.

In response, Applicants respectfully disagree that the teaching of the claimed receptor as a marker for monocytes of PBLs is not a specific and credible utility.

In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct. 1966), the U.S. Supreme Court reversed a holding of the Court of Customs and Patent Appeals (CCPA) finding of sufficient utility which in turn reversed the Board of Appeals' rejection for undisclosed utility. In *Brenner*, Manson was attempting to provoke an interference as the junior party with a patent application containing process claims directed to a process to create certain steroids. The Patent Office rejected the application because Manson had not disclosed any utility for the compound produced by the process. Manson tried to cure this defect by citing contemporaneous art indicating that the class of compounds (of which his compound was a member) were actively being screened as anti-tumor agents in mice, and that a homolog of Manson's molecule was effective in that role.

In rejecting the CCPA finding that process claims need not show utility for the product produced thereby, the Supreme Court held that "until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation."

Turning to the case at hand, the Examiner had made allegations that the utility cited by Applicants is neither specific nor substantial. In drawing analogies to ubiquitous tissue expression, molecular weight and chromosomal markers and analytical standards, there is an

implication of non-specific utility or the type of utility that was found insufficient in *Brenner*. In arguing that the application fails to disclose the claimed polypeptide as an HIV coreceptor, the Examiner implies that the disclosed utility as a PBL cell marker is not substantive or credible, and that a monopoly grant would be granting exclusivity without a compensating benefit to the public.

However, while the Examiner discusses "ubiquitous" utility and cell marker utility in the abstract - he nonetheless has not refuted the specificity of Applicants disclosure and assertion of utility as immunohistochemical diagnostics for monocytes and PBLs. Applicants do not assert a general or nonspecific prophetic utility as a molecular weight and tissue-specific marker. Applicants' utility is specific in that the polypeptide is specifically expressed on monocytes and PBLs. Applicants have "hard data" demonstrating this specific expression. Because of this specific expression, it has specific utility at least as a diagnostic marker for identifying and/or separating monocytes and/or PBLs from serum or other cellular material. The Examiner has not refuted why the asserted utility is not specific - or even why expression on specific tissue is not sufficient "specific" utility.

Next, the Examiner is dismissive of Applicants' assertion of utility allegedly because tissue-specific expression is not substantial. In commenting on the Bleuel *et al.* paper regarding the significance of the claimed receptor as an HIV co-receptor, and the absence of this recognition by Applicants, the Examiner is essentially saying that the subsequently disclosed therapeutic use is more substantial or of greater utility than Applicants' diagnostic use. The fact that a therapeutic utility was disclosed subsequent to Applicants' filing date is irrelevant to any analysis of the substantiality of Applicants disclosed diagnostic utility. The law has specifically admonished a rejection under 35 U.S.C. § 101 for requiring proof of therapeutic utility. *In re Malachowski*, 189, U.S.P.Q. 432, 435 (C.C.P.A. 1976); *In re Gottlieb and Ammann*, 140 U.S.P.Q. 665, 668 (C.C.P.A. 1964).

Continuing, there is no basis in the law for a utility rejection based on a "weighing of utilities." The mere fact that the subsequently disclosed utility is of greater interest than the utility asserted by Applicants must not be used to diminish or negate the propriety of the prior utility. There is no requirement for an Applicant to disclose *all* utilities 35 U.S.C. § 101 only *a* utility.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 20 to 23, 25 and 27 to 33.

The Rejection under 35 U.S.C. § 112

Claims 20 to 23, 25 and 27 to 33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

In response, the argument responsive to the above rejection is fully responsive to and disposes of this rejection.

Applicants believe that this application is now in condition for immediate allowance and respectfully request that the rejections be withdrawn and this case passed to issue.

The examiner is invited to contact the undersigned at (650) 225-1489 in order to expedite the resolution of any remaining issues.

Respectfully submitted,
GENENTECH, INC.

Date: Oct. 4, 2002

By: Craig G. Svoboda
Craig G. Svoboda
Reg. No. 39,044

09157
PATENT TRADEMARK OFFICE

1 DNA Way, MS 49
South San Francisco, CA 94080
Phone: (650) 225-1489
Fax: (650) 952-9881